COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 15/09/1999

C(1999) 3012

NOT FOR PUBLICATION

COMMISSION DECISION

of 15/09/1999
amending the marketing authorization for the
medicinal product for human use

"CETROTIDE - Cetrorelix (as acetate)"

Only the German text is authentic

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products,[1] as amended by Commission Regulation (EC) No 649/98,[2]

Having regard to Council Directive 92/27/EEC of 31 March 1992 on the labelling of medicinal products for human use and on package leaflets,[3] and in particular Article 10(3) thereof,

Having regard to the request to change the package leaflet concerning the medicinal product "CETROTIDE - Cetrorelix (as acetate)" entered in the Community register of medicinal products under Nos: EU/1/99/100/001-003, submitted on 19 May 1999 pursuant to Article 10(3) of the abovementioned Council Directive,

Whereas the proposed changes are not connected with the contents of the summary of characteristics of the medicinal product in question;

Whereas, moreover, the package leaflet as changed continue to comply with the requirements of Directive 92/27/EEC,

Whereas Decision C(1999) 939 of 13 April 1999 authorising the placing on the market of the medicinal product "CETROTIDE - Cetrorelix (as acetate)" should therefore be amended,

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1 OJ No L 214, 24. 8. 1993, p. 1.
2 OJ No L 88, 24.3.1998, p. 7.
3 OJ L 113, 30.04.1992, p. 8.

HAS ADOPTED THIS DECISION:

Article 1

Decision C(1999) 939 is hereby amended as follows:

Annex III B (package leaflet) is replaced by Annex I to this Decision.

Article 2

This Decision is addressed to ASTA Medica Aktiengesellschaft, An der Pikardie 10, 01227 Dresden, Deutschland.

Done at Brussels, 15/09/1999

For the Commission

Karel VAN MIERT
Member of the Commission